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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,572	08/05/2003	Christian Klein	2923-553	5439

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,572

Applicant(s)

KLEIN ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-18 and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it lacks an isolating step, i.e. there is no correlation between the preamble and the method steps.

Claim 2 is vague with respect to step d). It is unclear how the eluted complex of uncomplexed first binding partner is determined. It appears that the word "of" should be --or--.

Claims 13 and 14 are confusing because it appears to recite that the carrier matrix of claim 3 contains an aqueous liquid, i.e. the method claim 3 involves the use of a wet carrier matrix. Such a limitation does not have support in the specification as originally filed.

Claim 23 is confusing because it is unclear what is being detected. The claim recites contacting a sample which is suspected of containing a substance of interest with a matrix containing a first binding partner specific for *an analyte of said substance*, and a binding of the *analyte of said substance* to the first binding partner, follows by eluting any complexes and determining the identity of the substance by detecting the complexed or uncomplexed first binding partner. It is unclear what the *analyte of said substance* is, how it is defined and how its detection leads to the detection of the substance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8, 15-18 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek et al (DE 41 21 493 A1 - English Abstract) in view of Abuknesha et al (WO 93/11430).

Scholtissek discloses a method and device in which air to be examined is passed through a filter and any narcotic contained in the air is selectively adhered or absorbed on the filter. The adhered narcotic is eluted and dissolved in a solution and an antibody to the narcotic is mixed with the sample to detect the presence and amount of the narcotic. See English abstract.

Scholtissek differs from the instant invention in failing to teach a binding partner contained in the filter.

Abuknesha, however, discloses a device and method for collecting analyte in a gaseous medium. Abuknesha teaches that a binding partner for the analyte can be covalently linked or sorbed on to a carrier mean, i.e. a nitrocellulose membrane (pages 6 and 7) and the analyte from a gaseous phase is allowed to contact the binding partner and form a complex comprising the binding partner and the analyte. Abuknesha teaches the detection of complexed or uncomplexed binding partners as a measure of the analyte. Abuknesha also teaches a separation step as well as post reaction binding modification. See pages 12-21.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method taught by Scholtissek to include a binding agent in the carrier matrix such as taught by Abuknesha because Abuknesha teaches that it is well known in the art to include a reagent for capturing the analyte on a carrier means. A skilled artisan would have had a reasonable expectation of success in including a first capture reagent in a carrier matrix and using the carrier matrix to capture analyte in a gaseous sample because both Scholtissek and Abuknesha teaches using a filter material to capture analyte in gaseous samples, and Abuknesha teaches that the incorporation of binding partner into a carrier matrix is conventional and well known as well as providing a convenient means to effectively capture minute amount of trace narcotic in the air.

4. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek et al in view of Abuknesha et al as applied to claims 1-8, 15-18 and 23-27 above, and further in view of Schlipfenbacher et al (US 5,160,486).

The references of Scholtissek and Abuknesha have been discussed above. These references differ from the instant invention in failing to teach the liquid content of the carrier matrix.

Schlipfenbacher, however, teaches a test carrier for immunoassay comprising a fleece material. Schlipfenbacher discloses a variety of material with different water uptake and output properties. See column 10.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose any of the fleece material taught by Schlipfenbacher as the carrier means in the device and method taught by Scholtissek as modified by Abuknesha because Schlipfenbacher teaches that a special importance for the function of test carriers is the retention

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of water under certain defined experimental conditions, therefore, depending on the requirements of an assay, a skilled artisan would have had a reasonable expectation of success in choosing an appropriate fleece material according to the guidelines set forth by Schlipfenbacher. Furthermore, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable, and absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

5. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek in view of Abuknesha and Schlipfenbacher.

Even though these references fail to specifically state the gas permeability of the carrier matrix, they do teach carrier matrix permeable to gas and liquid, therefore, a skilled artisan would have a reasonable expectation of success in choosing the appropriate carrier matrix for use in the method and device of Scholtissek as modified by Abuknesha and Schlipfenbacher because it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of *Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims are for any

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particular purpose or solve any stated problem and the prior art teaches that the choice of an appropriate carrier matrix is dependent on the experimental conditions which often vary according to the sample being analyzed, various solutions and parameters appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

EP 520202 A2

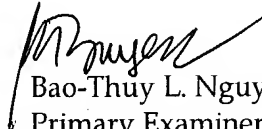
US 5,429,925

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
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10/19/04